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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/539,291

04/07/2006

Timothy Tak Yip

035394-0292

2464

22428 7590 02/23/2010

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EXAMINER

LIN, JERRY

ART UNIT

PAPER NUMBER

1631

MAIL DATE

DELIVERY MODE

02/23/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|-----------------------------------|--|
| Office Action Summary | Application No. 10/539,291 | Applicant(s) YIP ET AL. | |
| | Examiner JERRY LIN | Art Unit 1631 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 January 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-102 is/are pending in the application.
- 4a) Of the above claim(s) 1-83 and 88-102 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 84-87 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

Applicants' arguments, filed January 26, 2010, have been fully considered and they are deemed to be persuasive. However, upon consultation with a Supervisory Patent Examiner and reconsideration of the claims the following rejections are deemed necessary. The rejections constitute the complete set presently being applied to the instant application.

Status of the Claims

Claims 84-87 and biomarker WM-447 are under examination.

Claims 1-83 and 88-102 are withdrawn.

Drawings

The replacement drawings for Figure 1C were received on January 20, 2010. These drawings are accepted.

Claim Rejections - 35 USC § 112, 2nd Paragraph

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 84-87 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claims list the biomarkers using Cu(II) IMAC3 ProteinChip array format or the WCX ProteinChip array format. However these labels are set by the manufacturer of the ProteinChips. The manufacturer may change these labels in the future as they create different ProteinChips with different formats. Thus, the listed labels do not identify the biomarkers, and render the claims indefinite.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 84-87 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants have a described a method of qualifying lung carcinoma status in a subject using one or more listed biomarkers embodied in a tangible computer-readable medium . The specification describes various biomarkers which are used to qualify lung cancer status. These biomarkers are described as using the Cu(II) IMAC3 ProteinChip

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array format or the WCX ProteinChip array format. The specification provides the apparent molecular weight of each of the biomarkers (See Figures). While applicants have provided the molecular weights, applicants have not described chemical, physical, or other identifying characteristics. Furthermore, the provided molecular weights are insufficient to identify the biomarkers. If one of skill in the art were to perform the method, he or she would not know if the detected protein with the same molecular weight as those listed in claim 84 is the same protein as a protein listed in claim 84. Given the unpredictability of the biological sciences, one of skill in the art would need other identifying characteristics to verify if the proteins are the same.

In addition, the use of Cu(II) IMAC3 ProteinChip array format or the WCX ProteinChip array format to identify the protein is also insufficient to identify the biomarkers, because these labels are set by the manufacturer of the ProteinChips. The manufacturer may change these labels in the future as they create different ProteinChips with different formats. One of skill in the art would face further difficulty with determining if detected proteins are the same as those listed in the claims. Thus, specification does not describe the biomarkers in such a way as to reasonably convey to one skilled in the art that the inventors had possession of the claimed invention.

6. Claims 84-87 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to

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which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary; (2) the amount of direction presented; (3) the presence or absence of working examples; (4) the nature of the invention; (5) the state of the prior art; (6) the relative skill of those in the art; (7) the predictability or unpredictability of the art; (8) the breadth of the claims. While each factor is not explicitly discussed, each factor has been considered and the relevant factors as discussed below.

The claims are drawn to a method of qualifying lung carcinoma status in a subject using one or more listed biomarkers embodied in a tangible computer-readable medium. However, specification recites that a detection of a pattern of these biomarkers allows the user to qualify lung carcinoma status (Specification, paragraphs 0006-0021). Only markers WM-446 and WM-447 are identified as markers capable of identifying lung cancer by themselves (paragraph 0011). The specification does not teach or show working examples of using the other biomarkers identifying lung carcinoma by themselves. Given that the art is unpredictable, one of skill in the art would have to perform undue experimentation in order to determine if any of these biomarkers are capable of identifying lung carcinoma by themselves.

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In addition, because the biomarkers are listed in way that one of skill in the art could not verify if a detected protein was the same as a biomarker (see above), one of skill in the art must perform undue experimentation to determine if the detected protein was a biomarker of lung carcinoma.

Withdrawn Rejections

Applicant's arguments and amendments, filed January 20, 2010, with respect to the rejections made under 35 U.S.C§101 have been fully considered and are persuasive. The amendments are sufficient to overcome these rejections. These rejections have been withdrawn.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JERRY LIN whose telephone number is (571)272-2561. The examiner can normally be reached on 7:30-6:00pm, M-TH.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie A. Moran can be reached on (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jerry Lin/
Primary Examiner, Art Unit 1631
2/22/2010